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| 10/605,104 | 09/09/2003 | Michael Knoblauch | 11154US.GAS | 2103 |
| 366/08 7590 04/01/2009 GUDRUN E. HUCKETT DRAUDT SCHUBERTSTR. 15A WUPPERTAL, 42289 GERMANY | | | | |
| EXAMINER | | | | |
| TSAY, MARSHA M | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/605,104

Applicant(s)

KNOBLAUCH ET AL.

Examiner

Marsha M. Tsay

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-893)
Paper No(s)/Mail Date 02.06.04; 03.04.04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicant's election without traverse of Group I, claims 1-15, to SEQ ID NO: 2, in the reply filed on January 14, 2009 is acknowledged. Further, Applicants' remarks regarding the species election of one SEQ ID NO. is persuasive; therefore, the species election is withdrawn.

Claims 16-20 have been withdrawn from further consideration by the Examiner because they are drawn to non-elected inventions. Claims 1-15, to SEQ ID NOS: 1-5, are currently under examination.

Priority: The request for priority to GERMANY 102 41 681.8, filed September 9, 2002, is acknowledged.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-15, as written, do not sufficiently distinguish over protein bodies (forisomes) that exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206, USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified". See MPEP 2105. As currently written, the term "derivable" does not indicate the "hand of man"

since it is unclear what is meant by "derivable" and further said "derivable" could be interpreted to mean capable of being derived or, i.e. not yet derived.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 1, recites "derivable". It is unclear what is meant by the term "derivable", i.e. isolated, etc. Further clarification is requested.

Claims 8-11 recite comprising or consisting of at least one of the sequences of SEQ ID NOS: 1 and 2. The phrase "consisting of at least one" is confusing since "consisting" is interpreted to be closed language and does not allow for additional sequences.

Claims 13 and 15 recite further containing at least one of the following amino acid sequences, i.e. SEQ ID NO: 1 and 2. The claims are dependent on claims 12 and 14, which recite a protein or protein fragment comprising or consisting of the sequences, i.e. SEQ ID NOS: 3, 4, and 5. If claims 12 and 14 are drawn to proteins consisting of the sequences SEQ ID NOS: 3, 4, and 5, the use of closed language "consisting" does not allow for additional sequences or residues to be appended onto the protein or protein fragment. Therefore, claims 13 and 15 should clarify that further containing the additional sequences of SEQ ID NO: 1 and/or 2 only pertains to the proteins comprising SEQ ID NOS: 3-5.

Claims 2-7, 12, and 14 are included in this rejection because they are drawn to non-elected inventions and fail to cure the defect.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Knoblauch et al. (2003 Nature Materials 2: 600-603). Knoblauch et al. teach forisomes isolated from *Vicia faba* sieve elements (p. 600). Knoblauch et al. teach that intact forisomes have a length that varied between 18 and 34 μm and diameter between 2.2 and 4 μm (p. 600; claims 1-2, 4). In the presence of Ca^{2+} , forisomes responded with longitudinal contraction by about 30% and increased in diameter by $119.5\% \pm 47.9\%$ (p. 600, also Fig. 1; claims 1-2, 4-5, 7). Further, at a pH above 9.6, the forisomes (protein bodies) swelled radially and contracted gradually and reversibly (p. 601, also Fig. 3; claims 1). While Knoblauch et al. do not explicitly teach the MW of the forisomes, the MW ranges disclosed in claims 2 and 5 are believed to be anticipated by the forisomes of Knoblauch et al., since the physical properties of the Knoblauch et al. forisomes meet the limitations recited in instant claim 1, i.e. both are “derivable” from Fabaceae and have a length of approximately 1 to 40 μm and a diameter of approximately 1 to 10 μm . Further, regarding claims 3 and 6, it should be noted that the claims are drawn to the protein body;

therefore, since the forisomes of Knoblauch et al. meet the physical characteristics described in claim 1, the peptides should be present in said forisomes of Knoblauch et al.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Knoblauch et al. (2001 The Plant Cell 13: 1221-1230; IDS). Knoblauch et al. teach crystalline P-proteins are found in sieve elements of Fabaceae leaves (p. 1222). On page 1, the instant specification discloses forisomes are protein bodies which are also referred to as crystalline P-proteins (p. 1 [0002]). The crystalline P-proteins appeared as elongate electron-dense bodies, up to 30 μm long and 2 to 6 μm wide (p. 1222, Fig. 1A; claims 1-2, 4-5, 7). While Knoblauch et al. do not teach all the elements recited in the instant claims, these elements are believed to be present in the forisomes of Knoblauch et al. when subjected to Ca^{2+} treatment and a basic pH environment since the instant forisomes and the Knoblauch et al. forisomes are both derivable from Fabaceae and have a length of approximately 1 to 40 μm and a diameter of approximately 1 to 10 μm . Further, regarding claims 3 and 6, it should be noted that the claims are drawn to the protein body; therefore, since the forisomes of Knoblauch et al. meet the instant characteristics of being derivable from Fabaceae and having a length of approximately 1 to 40 μm and a diameter of approximately 1 to 10 μm , the peptides should be present in said forisomes of Knoblauch et al.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

March 26, 2009

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